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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/702,319	11/06/2003	Ranjan Perera	ARBG-004/07US 307197-2038	7997
58349 7590 12/11/2009 COOLEY GODWARD KRONISH LLP ATTN: Patent Group Suite 1100 777 - 6th Street, NW WASHINGTON, DC 20001				
EXAMINER				
QIAN, CELINE X				
ART UNIT		PAPER NUMBER		
1636				
MAIL DATE		DELIVERY MODE		
12/11/2009		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/702,319

Applicant(s)

PERERA ET AL.

Examiner

CELINE X. QIAN

Art Unit

1636

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 22-40 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 22-40 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 06 November 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/226)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: ____
- Paper No(s)/Mail Date ____

DETAILED ACTION

Claims 22-40 are pending in the application.

This Office Action is in response to the Amendment filed on 8/3/09.

Response to Amendment

All objections and rejections not reiterated in this office action have been withdrawn.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 38 and 40 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue." These factors include, but are not limited to: (a) the nature of the invention; (b) the breadth of the claims; (c) the state of the prior art; (d) the amount of direction provided by the inventor; (e) the existence of working examples; (f) the relative skill of those in the art; (g) whether the quantity of experimentation needed to make or use the invention based on the content of the disclosure is "undue"; and (h) the level of predictability in the art (MPEP 2164.01 (a)).

The nature of the invention

The claim is drawn to an isolated polynucleotide sequence comprising a sequence selected from the group of: a polynucleotide comprising a 20-600 mer of SEQ ID NO: 12, 60, or nucleotides 1-1643 of SEQ ID NO: 113.

The teaching of the specification and the breadth of the claim

The instant specification teaches SEQ ID NO: 12, 60 and 1-1643 of SEQ ID NO: 1643 are promoter from cOMT gene of *E. grandis* that directs vascular specific promoter function. However, the specification does not disclose fragments as short as 20-mer which also possess such activity. The claimed scope is broad because it encompasses any fragments ranging from 20-600 of the claimed sequences which may or may not have promoter activity. Although the specification teaches the sequences of SEQ ID NO: 12, 60 and 113, a skilled artisan would not know how to use said fragments.

The state of prior art and the level of predictability in the art

The state of art at the time of filing is silent on the utility for the claimed fragments. The state of art at the time of filing does not teach any fragments of varying length from a known promoter would automatically have a known utility. As such, the skilled artisan would have to rely on the teaching of the specification to make and use the invention as claimed. Since the specification does not teach how to use such 20-600mer except being part of a promoter, one of skilled in the art would have to engage in undue experimentation to use the claimed fragments. Therefore, the claimed fragments of SEQ ID NO: 12, 60 and 113 is not enabled by the instant specification.

The newly added claim 40 is rejected for same reason as stated above.

Response to Arguments

In response to this rejection, Applicants argue that claim 38 does not require the isolated polynucleotide to have functional promoter activity. Applicants assert the amended claim now recites 20 mers to 600 mers that are complementary to SEQ ID NO: 12, SEQ ID NO: 60 or 1-1643 of SEQ ID NO: 113. Applicants argue that such fragments can be used as probes and primers, as well as constructs for promoter silencing. Applicants thus conclude that the claimed fragments are enabled by the instant specification.

The above argument has been fully considered but deemed unpersuasive. Using polynucleotide for the purpose of being a primer or probe is not itself a substantial and specific utility because any polynucleotide can be used for this purpose. Moreover, it is unclear how a polynucleotide comprising 20-600mer in a construct comprising a promoter sequence and a gene termination sequence may be used to silent said promoter. As state in the previous office action, the specification only enables the functional fragments of the cOMT promoter that have promoter function. Therefore, this rejection is maintained and also applies to the newly added claim 40.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 22-40 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-10 of U.S. Patent No. 7365186. Although the conflicting claims are not identical, they are not patentably distinct from each other because they overlap in scope that they are both directed to isolated polynucleotide that confers vascular specific gene expression in a plant cell. The polynucleotide sequence of SEQ ID NO: 1-6 in the '186 patent, and functional fragments thereof, are part of the sequence contained in SEQ ID NO: 113, and they direct vascular specific gene expression in plant cells. Since the '186 patent discloses in the preferred embodiments of using the claimed promoter, functional fragments thereof to generate transgenic plant that can identify genes responsible for a desired function based on the increase or decrease in lignification (see [32]-[36] of the patent), claims 35-37 of the instant application are obvious in view of such teaching. Therefore, claims 22-39 are rejected for double patenting.

In response to this rejection, Applicants argue that the present claims dominate the claim of the '186 patent, wherein the instant application contain broader claims which encompass the invention claimed in a narrower or more specific manner in the '186 patent. Applicants further assert granting a patent to the instant application will expire on March 25, 2019 plus any term adjustment, this date ends before the '186 patent, which expires on 11/7/2023. Applicants argue

that granting a patent to this application without a terminal disclaimer does not unjustly extend the rights as a result of earlier termination.

The above arguments have been fully considered but deemed unpersuasive. Claims 22 of the instant application is drawn to an isolated polynucleotide comprising the sequence of 1525-1643 of SEQ ID NO: 113, which comprises a functional vascular tissue specific *E. grandis* cOMT promoter. Claim 1 of the '186 patent is drawn to an isolated polynucleotide selected from the group consisting SEQ ID NO: 1-6, wherein SEQ ID NO: 1-4 comprises the sequence of 1525-1643 of SEQ ID NO: 113 of the instant application, and SEQ ID NO: 5 consists the sequence of 1525-1643 of SEQ ID NO: 113. As such, the claimed polynucleotides have overlapping scope, and are not patentably distinct from each other. This situation is not domination as defined in MPEP section 804, but obviousness double patenting. In response to Applicants' arguments directed to no extension of the '186 patent, Applicants are reminded that ODP not only prevents unjustly extends the rights beyond the term, it also keeps patentably indistinct subject matter together. Moreover, 11/7/2023 is the date of expiration of the '186 patent only when all maintenance fees are paid. Otherwise, the term would expire on the maintenance fee payment due date, and granting this application without a terminal disclaimer would have extended the rights unjustly under this circumstance. Therefore, this rejection is maintained for reason set forth of the record mailed on 5/1/09 and discussed above.

Conclusion

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CELINE X. QIAN whose telephone number is (571)272-0777. The examiner can normally be reached on 10-6:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from

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a USPTO Customer Service Representative or access to the automated information system, call
800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Celine X Qian /

Primary Examiner, Art Unit 1636